IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO:** ***WAVE 1 CASES***	**Master File No. 2:12-MD-02327** **MDL No. 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

PLAINTIFFS' RESPONSE IN OPPOSITION TO DEFENDANTS' MOTION TO EXCLUDE CERTAIN OPINIONS OF JOHN MIKLOS, M.D.

COMES NOW, the Plaintiffs in the above-styled action, and file their Response in Opposition to Defendants Ethicon, Inc.'s and Johnson & Johnson's (hereinafter referred to as "Defendants") Motion to Exclude Certain Opinions of John Miklos, M.D. (hereinafter referred to as "Dr. Miklos"), and show the following:

INTRODUCTION

Plaintiffs have retained Dr. Miklos to provide general liability expert opinions with regard to the Defendants' TVT-Secur (or TVT-S) products at issue in certain of these Wave cases.

The TVT-Secur is a single-incision sling sold for treatment of stress urinary incontinence, which the Defendants withdrew from the market after the FDA issued a "522 Order" in January 2012 requiring clinical studies to demonstrate the safety and efficacy of the device. (Miklos Report, p. 12).

Dr. Miklos is a world-renowned, Board-certified pelvic floor surgeon who has implanted thousands *and* removed hundreds of polypropylene transvaginal pelvic mesh products. A copy of Dr. Miklos's Curriculum Vitae and Expert Report are attached to Defendants' Motion as

Exhibits B and C, respectively. Because Defendants only included excerpted portions of his deposition, a copy of Dr. Miklos's deposition taken in this MDL is attached hereto as **Exhibit 1**. He was one of the first surgeons in the country to perform a transvaginal mesh kit procedure, and he was a forerunner in teaching other surgeons how to perform such procedures. Dr. Miklos has served as a peer reviewer for several of the top national and international medical journals in the fields of obstetrics and gynecology, urogynecology, and female pelvic medicine. In forming his opinions, Dr. Miklos has not only reviewed an extensive body of published literature on pelvic mesh devices, but he relies on his own peer-reviewed, published studies on the topics of mesh and mesh-related complications. Of his extensive peer-reviewed publications, Dr. Miklos has authored or co-authored 25 papers and 9 book chapters specific to synthetic or allogenic grafts for pelvic floor surgery or stress urinary incontinence. Among his several studies specific to pelvic repair devices, Dr. Miklos co-authored the three largest known studies on mesh complications, which were presented as abstracts at the 2014 AUGS/IUGA meeting. One of these three studies, recently published in the International Urogynecology Journal (2016), is the largest published manuscript on the subject of mesh complications. (Miklos Report, pp. 1-7).

Despite Defendants' attempts to diminish his qualifications, it is clear that he is not simply a user of transvaginal mesh devices (including several of those products sold by Defendants), but also a prior advisor and consultant of several transvaginal mesh device manufacturers, *including* the Defendants. (Miklos Report, pp. 3-7).

Specifically with respect to these Defendants, Dr. Miklos was trained by Defendants on the TVT retropubic sling in Sweden in 1998. He was one of the first six surgeons in the United States to implant the TVT. Dr. Miklos was an advisor and preceptor on the retropubic TVT sling

until approximately 2002, and he estimates that he taught more than 400 surgeons how to implant the TVT sling. (Miklos Report, p. 3).

Dr. Miklos was also invited by Defendants to travel (at Defendants' expense) to France to meet with the developers of the Prolift device to evaluate the Prolift in a clinical and a laboratory setting. As a result of this consultation, Dr. Miklos explained to the Defendants that the surgery was too dangerous to perform and to teach to other surgeons. (Miklos Report, p. 4).

Dr. Miklos was also invited by Defendants to travel to Belgium to evaluate the TVT-O device, and he attended a cadaver training course for the TVT-O device at which he discussed the pros and cons of the TVT-O with the Defendants' representatives in attendance. (Miklos Report, p. 4).

In 2006, Defendants invited Dr. Miklos to attend a cadaver training session on the TVT-S with one of Defendants' Key Opinion Leaders, Dr. Vincent Lucente. Dr. Miklos discussed with the Defendants several design issues with respect to the TVT-S device, including many of the same design flaws as to which he offers opinions in these cases. At the invitation of Dr. Lucente, Dr. Miklos participated in a clinical study intended to address the safety and efficacy of the TVT-S device. Dr. Miklos discusses the results of that study in his Expert Report. As a result of his experience in this study, Dr. Miklos states that he could not support the TVT-S for use in treatment of stress urinary incontinence and he ceased using the product. (Miklos Report, p. 5).

Of the more than 700 mesh devices that Dr. Miklos has removed from patients, he has removed a number of TVT-S meshes. (Miklos Report, pp. 6-7).

ARGUMENT

I. DR. MIKLOS' KNOWLEDGE, SKILL, EXPERIENCE, TRAINING, AND EDUCATION QUALIFY HIM TO RENDER HIS OPINIONS REGARDING THE DEFECTIVE DESIGN OF THE TVT-SECUR.

As set forth above and more fully in his Expert Report and Curriculum Vitae, Dr. Miklos is not merely one of the world's preeminent expert urogynecologists in the use of pelvic repair mesh and in the understanding and treatment of mesh complications, he was actually consulted by Ethicon with respect to the design of the TVT-S device. Dr. Miklos also participated in an Ethicon-sponsored clinical study of the TVT-S device at the invitation of one of Ethicon's Key Opinion Leaders, Dr. Vincent Lucente. Thus, for Ethicon to challenge Dr. Miklos's "qualifications" to offer opinions regarding the TVT-S device is disingenuous.

The fundamental problem with Defendants' contentions with respect to Dr. Miklos's alleged lack of "qualifications" is that several of the opinions that Defendants seek to challenge here do not appear anywhere in Dr. Miklos's Report. Instead of directly challenging the design defect opinions that Dr. Miklos actually contained in his Report in this MDL,[1] Defendants seek to raise questions about Dr. Miklos's ability to offer opinions regarding "laser cut mesh/fraying" and the TVT-S's "Ethisorb fixation mechanism." (Defendants' Brief, pp. 3-6). However, these defects are not mentioned anywhere in Dr. Miklos's Report in this case. The fact that the Defendants would file a motion and supporting brief challenging opinions that are not even proffered in this MDL speaks to the invalidity of the Defendants' arguments generally.[2]

[1] Dr. Miklos's design defect opinions, set forth in pages 13-14 of his Report, are focused primarily on the insertion device, the anchoring mechanism (which can become dislodged after removal), tissue or organ damage upon insertion, and the difficulty in properly tensioning and/or removing the device. He more fully addressed his design criticisms in his deposition. (Miklos 4/8/16 depo., 54:3-56:16).

[2] It would appear that the Defendants simply cut-and-pasted from a prior brief from a Texas State court case wherein Dr. Miklos was named as an expert for a TVT-S plaintiff, and cites repeatedly to Dr. Miklos's deposition testimony from that state court action. Underscoring the fact that it has no valid

Instructively – and Plaintiffs submit conclusively – Defendants fail to substantively address any of the actual design defect opinions offered by Dr. Miklos, with the exception of a single sentence in the last paragraph of Section I of their Brief, which baldly claims that Dr. Miklos "cites no supporting literature." (Defendants' Brief, p. 6). Contrary to Defendants' argument, Dr. Miklos's design opinions that are actually contained in his Expert Report are supported not only by his extensive knowledge, training and experience with pelvic repair mesh products generally, and his familiarity with the published literature (including the published TVT-S literature), but by his knowledge, training and experience with the TVT-S device specifically. Not only was Dr. Miklos trained by Ethicon regarding the TVT-S, he was also asked to participate in a TVT-S cadaver lab and consulted by Ethicon specifically regarding the design of the TVT-S. Moreover, Dr. Miklos participated in a clinical study of the TVT-S device sponsored by Defendants. Defendants' cursory challenge to Dr. Miklos's design defect opinions are ill-founded.

Defendants' argument on page 5 of their Brief serves to illustrate the fundamental flaw of their position with respect to Dr. Miklos. In that section, the Defendants urge that because Dr. Miklos did not "publicly disavow" the published efficacy rates from the TVT-S clinical study in which he participated, he must somehow be held to support those conclusions. (Defendants' Brief, p. 5). As Dr. Miklos explained in his deposition, the author of that study, Ethicon's preceptor Dr. Vincent Lucente, had a 69% "success rate" in this study. (Miklos 4/8/16 depo., 30:3-7). Defendants further urge that Dr. Miklos has now abandoned a previously "touted" personal "success rate" with the TVT-S "averag[ing] in the 60-70%" range, and thereby imply

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challenge of Dr. Miklos's opinions set forth in his Expert Report in this MDL, Defendants resort to challenging opinions that apparently were offered in the state court case. Plaintiffs will not waste time addressing these wholly irrelevant challenges except to point out that they are misplaced here.

that he must be held to support these previously "touted" success rates. (Defendants' Brief, p. 5). Apparently, Defendants do not recognize the import of their own argument: the published success rates from the study in which Dr. Miklos participated were scientifically and objectively *terrible*. A 60-70% "success rate" means that 30-40% of the procedures were **failures**. Arguing that Dr. Miklos should be held to a failure rate of 30-40% only serves to bolster his opinions regarding this abject failure of a device, not undermine his testimony or opinions.

In short, it appears that the essence of Defendants' challenge to Dr. Miklos's design defect opinions is that there are some published articles that the defense would represent as supportive of the TVT-Secur. (Defendants' Brief, p. 6). It is unnecessary to substantively address any of the articles that Defendants believe would support the TVT-S, none of which are specifically mentioned or discussed in their Brief. Suffice it to show that while the presence or absence of literature that is alleged to contradict expert's opinion may provide a basis for cross-examination at trial, it is not a valid ground for a *Daubert* motion.[3]

II. DR. MIKLOS' OPINIONS REGARDING SAFER FEASIBLE ALTERNATIVES TO THE TVT-SECUR ARE RELIABLE.

Defendants' next misguided challenge to Dr. Miklos is with respect to his opinion that there were other safer alternatives to the TVT-S device, specifically retropubic and "inside-out" transobturator slings. Defendants urge that because Dr. Miklos did not conduct any "testing, calculations, engineering analysis, or publications," his opinion that other SUI products were safer and equally or more effective should be disregarded entirely. (Defendants' Brief, p. 7). Defendants' argument is wholly without support, as shown below.

[3] The Defendants make no assertion here that Dr. Miklos failed to review or address any allegedly contradictory literature; they simply argue that contradictory articles exist. Indeed, Dr. Miklos was questioned extensively in his deposition here about the published TVT-S literature. (Miklos 4/8/16 depo., 28:9-37:16). Instructively, Defendants hardly mention any of his deposition testimony from this MDL.

First, it is necessary to point out the hypocrisy of Defendants' contention that an expert should be precluded from testifying to the existence of a safer feasible alternative product because of the alleged non-existence of "testing, calculations, engineering analysis, or publications" to establish the safety or efficacy of the alternative device. If that were so, then Ethicon could never have any expert testify regarding the alleged safety or efficacy of the TVT-S because such was never established by any "testing, calculations, engineering analysis, or publications" prior to the launch of this unreasonably dangerous device. As set forth in Dr. Miklos's Report, the TVT-S was launched with no clinical data, and was ultimately removed from the market due to regulatory scrutiny in the United Kingdom, Australia, and the United States due to lack of demonstrated efficacy and safety concerns. (Miklos Report, pp. 8-12). As set forth in Dr. Miklos's Report, Ethicon's own internal communications reflect the company's knowledge that the TVT-S showed "high failure rates across multiple centers" in 2007 (Miklos Report, pp. 8-9 (citing ETH.MESH.00642330), and that "[t]here is no documentation that [the TVT-S] is safer and with equal efficacy as TVT." (Miklos Report, p. 11 (citing ETH.MESH.04048515)). In fact, Ethicon's own internal documents state that "the TVT-Secur is associated with inferior patient-reported and objective cure rates at 1 year, and higher reoperation rates when compared to standard mid-urethral sling (e.g., TVT/TVT-O)." (Miklos Report, p. 9 (citing ETH.MESH.05600922)). Defendants criticism of Dr. Miklos for allegedly not citing supporting data demonstrating the safety of alternative products simply underscores the glaring fact that Defendants never had any data demonstrating the safety of the TVT-S before selling the product to be implanted into women's bodies throughout the world.

Further, Defendants' argument fails because Dr. Miklos did, in fact, conduct a study regarding the efficacy of the TVT-Secur device. He participated in an Ethicon-sponsored TVT-S

study at the invitation of Ethicon thought leader surgeon. In his own clinical experience with this product, conducted as part of Ethicon's own clinical study, Dr. Miklos personally had a failure rate of 21% after only six weeks, which he explained "never gets better, it only goes down" over time, and "is nothing in the world of surgery." (Miklos 4/8/16 depo., 27:16-28:8). He explained that his coordinator in the study, Dr. Vincent Lucente, had a failure rate of 31.5%. *Id.* Because the failure rate for the retropubic TVT was significantly less (between 5-10%), Dr. Miklos "had to stop [his participation in the clinical study] because it wasn't the right thing for my patients…It wasn't beneficial, it wasn't efficacious, and it wasn't the right thing to do." *Id.*

Defendants throw a conclusory statement in their Brief to the effect that the Court has previously excluded testimony from an expert who "acknowledges that medical literature contrary to that [expert's] opinion but failed to explain why he or she disagreed with it." (Defendants' Brief, p. 7).[4] This puzzling argument fails for the simple reason that Defendants have not pointed to and cannot point to any allegedly "contrary" literature that Dr. Miklos supposedly "failed to explain." In the exhibits attached to his Report, Dr. Miklos cites to a volume of articles and publications that he reviewed in forming his opinions, including numerous articles that relate specifically to the TVT-S. (An excerpted copy of the list of articles contained in Dr. Miklos's review materials, which were served on Defendants with his Expert Report, is attached hereto as **Exhibit 2**). Furthermore, Dr. Miklos was questioned on his deposition about

[4] Even if Dr. Miklos had not reviewed a particular article, that would not provide a basis for a *Daubert* challenge. The Court has held that merely pointing to an article that the expert did not review may be a proper subject for cross-examination, but it will not serve to exclude the expert's opinions. *Carlson v. Boston Scientific Corp.*, 2015 WL 1931311, *12 (S.D.W.Va. 2015) (denying defense motion to exclude plaintiff's urogynecologist expert based on his having reviewed only one device-specific article, and stating "if there are certain device-specific publications that [plaintiff's urogynecologist expert] failed to review in preparing his expert report, [defendant] is free to inquire about those publications on cross-examination."). Here, however, the record reflects that Dr. Miklos *did* review the relevant TVT-S literature, and he *did* address this subject in his testimony. The fact that Defendants apparently did not like his testimony does not mean that his testimony can be excluded.

literature that Defendants contend "report satisfactory efficacy with TVT-Secur," and Dr. Miklos testified extensively and in detail about the published TVT-S literature in his deposition. (Miklos 4/8/16 depo., 28:9-37:16).[5] Defendants' attack on Dr. Miklos's opinions is, again, not founded on any evidence.

Finally, Defendants summarily assert that "Dr. Miklos's opinion should be excluded because he cannot point to any reliable, verifiable basis for the comparison of safety rates of TVT-Secur versus these other products." (Defendants' Brief, p. 8). Such argument, again, is flatly contrary to the evidence in this case. Dr. Miklos discusses several published studies in his Expert Report, including a study conducted by Ethicon's own Medical Director, Piet Hinoul, which demonstrated significantly lower efficacy rates with the TVT-S versus TVT-O. (Miklos Report, p. 11). Dr. Miklos's Report also discusses several other TVT-S studies demonstrating the relative lack of safety and efficacy vis-à-vis other available devices, including a Level 1a Cochrane Review which concluded that "TVT-Secur is inferior to standard mid-urethral slings for the treatment of women with stress urinary incontinence and has already been withdrawn from clinical use." (Miklos Report, pp. 8-12). The only "safety rate" that Dr. Miklos was questioned about in his deposition (and the only "safety rate" mentioned in the Defendants' Brief) was the rate of erosion. However, as Dr. Miklos explained in his deposition, simply comparing the erosion rate is not a valid comparison in terms of the safety and effectiveness of the device. Dr. Miklos explained that looking at the rates for one complication (erosion, which was not even a primary endpoint of any of the published studies discussed) is no way to evaluate the TVT-S, particularly when the lack of efficacy with TVT-S led patients back into the operating room for another procedure. (Miklos 4/8/16 depo., 52:22-53:18). Dr. Miklos later

[5] Just some of the data and literature that was published and available to Ethicon beginning at least in 2007 reporting unacceptable failure and complication rates are discussed in Dr. Miklos's Expert Report. (Miklos Report, pp. 8-13).

explained that even though post-operative complications and complication rates are not the focus of most published studies, published literature demonstrates a higher rate of certain complications (such as urethral and bladder perforations) with the TVT-Secur compared with other products. (*Id.*, 62:6-64:15). Dr. Miklos further testified that "defective design to me means that your risk outweighs the benefit with the product that's in your hands," and he explained the unique design characteristics of the TVT-S that made the design more dangerous than other SUI devices (including the increased trauma and scar tissue formation due to the insertion device, and the releasing mechanism), with less effectiveness than other products. (*Id.*, 54:3-56:16).

III. DEFENDANTS' CHALLENGE TO DR. MIKLOS' OPINIONS REGARDING THE INADEQUATE TVT-SECUR IFU IS ILL-FOUNDED.

Defendants' challenge to Dr. Miklos's warnings opinions is misguided. Since 1998, Dr. Miklos has gained extensive hands on training by reading, reviewing, and advising patients in Instructions for Use (IFU's) from an array of transvaginal mesh devices. (Miklos Report at 7, 14). Dr. Miklos has regularly consulted with pelvic mesh manufacturers for many years regarding the design of their products, including these Defendants. (*Id.*, pp. 3-7). Dr. Miklos has reviewed Defendants' IFU for the TVT-S and is intimately familiar with TVT-Secur device, having attended Ethicon cadaver labs, and even participating in an Ethicon-sponsored TVT-S clinical study. As such, Dr. Miklos is certainly an expert on warnings *from a surgeon's perspective*.

Dr. Miklos does not purport to offer warnings opinions outside of his realm of expertise. His position with regard to the IFU and warnings contained therein is clear: he is offering opinions with regard to the information upon which physicians regularly and reasonably rely, and information regarding the proper implantation technique in order to minimize risks and complications. (Miklos Report, pp. 14-16; 18-24). Dr. Miklos is highly-credentialed,

experienced and capable of testifying about physician expectations and what warnings should and/or should not be contained within an IFU so that patients receiving the device can be properly counseled. Likewise, Dr. Miklos is well-qualified to testify about the adequacy of the instructional information provided in the IFU regarding how surgeons were instructed to use the device. In short, Dr. Miklos is qualified to offer opinions regarding expectations of warnings from the standpoint of a physician who implants and removes transvaginal mesh products.

An expert urogynecologist is able to opine on adequacy of warnings contained within a medical product's IFU. *Edwards v. Ethicon, Inc.*, 2014 WL 3361923 at *13 (2:12-cv-01378 [Dkt. 139] S.D.W.V. July 8, 2014). In *In re Yasmin and Yaz (Drospirenone) Prods. Liab. Litig.*, 2011 WL 6301625, *11-*13 (S.D.Ill.2011), the drug manufacturer argued that the plaintiffs' proffered experts, both Obstetrician-Gynecologists, were not qualified to offer opinions regarding the adequacy of its labeling, and further that their opinions were not based on any reliable methodology. The Court rejected its argument, and held instructively as to one of the OB-GYN experts as follows:

> As a practicing OB/GYN tasked with making prescription decisions on a daily basis, Dr. Bercy-Roberson is qualified to opine as to how certain knowledge, obtained through studies, reports, and internal Bayer documents, would have affected her previous prescription-related decisions. Dr. Bercy-Roberson does not require expertise in FDA regulations to opine in this manner, as she does not comment on the conduct of the FDA. Further, doctors are 'fully qualified to opine on the medical facts and science regarding the risks and benefits of [drugs]…and to compare that knowledge with what was provided in the text of labeling and warnings for FDA approved drugs.' *In re Diet Drugs Prods. Liab. Litig.*, MDL 1203, 2000 WL 876900, *11 (E.D.Pa. June 20, 2000). Thus, Dr. Bercy-Roberson is qualfied to render an opinion as to the drug label's completeness and accurateness. *See id*....
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> Thus, as Dr. Bercy-Roberson's opinion based on peer-reviewed sources and data, her methodology is sound. The correctness of her opinion is left to the trier of fact's determination.[6]

[6] The same holding with respect to the Plaintiffs other proffered OB-GYN expert in the *Yaz* MDL (Anthony Disciullo) – based on his extensive clinical experience and review of peer-reviewed literature

See also Smith v. Wyeth-Ayerst Laboratories Co., 278 F.Supp.2d 684, 702 (W.D.N.C. 2003) (citing *In re: Diet* Drug MDL PTO 1332, where the MDL court concluded physicians are "'qualified to render an opinion as to the labels' completeness, accuracy, and . . . the extent to which any inaccuracies or omissions could either deprive a reader or mislead a reader of what the risks and benefits . . . are or were at the time the labeling was published.'…"); *Accord, Burton v. Wyeth-Ayerst Labs. Div. of Amer. Home Prods. Corp.*, 513 F.Supp.2d 708, 712 (N.D.Tex.2007); *In re Rezulin Prods. Liab. Litig.*, 309 F.Supp.2d 531, 556 (S.D.N.Y.2004) ("Pursuant to the defendants' concession [in light of *In re: Diet Drugs*], and subject to relevance rulings to be made by the trial courts, these [physician expert] witnesses are not precluded from offering otherwise admissible testimony as to the accuracy of the Rezulin label."); *In re Baycol Prods. Litig.*, 532 F.Supp.2d 1029, 1063-64 (D.Minn.2007) (citing *In re: Diet Drugs* opinion in denying defense *Daubert* motion to exclude physician expert opinion regarding drug labeling, stating "The Court agrees that [the plaintiffs' physician expert] is qualified to render an opinion regarding the completeness or accuracy of the Baycol label based on his knowledge of the risks of Baycol and his own clinical experience.").

Contrary to Defendants' argument here, a urogynecologist expert is not prohibited from offering an opinion on the adequacy of a medical device IFU solely on the basis that he is not a so-called "warnings expert." *Edwards*, 2014 WL 3361923 at *13. If that were the law, then none of Defendants' physician experts could ever testify regarding the alleged adequacy of their products' warnings because they are likewise not "warnings experts." Such a holding would also ignore the reality that these products were marketed to and implanted by physicians; no purported "warnings expert" could be expected to know and testify as to what a physician would

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and company documents, he was qualified to offer opinions as to the adequacy of the drug warning label, and his opinions were reliable.

expect to be contained within the instructions for use for a product used exclusively by doctors. As this Court explained in *Edwards*, "Dr. Blaivas [an expert urogynecologist] need not be an expert on product warnings per se. Rather, as a urologist, Dr. Blaivas is qualified to testify about the risks of implanting the TVT-O and whether those risk were adequately expressed on the TVT-O's IFU." *Edwards*, 2014 WL 3361923 at *13. Furthermore, an expert need not have drafted the IFU to opine on its adequacy. *Huskey v. Ethicon, Inc.*, 2014 WL 3362264 at *5 (2:12-cv-05201 [Dkt. 271] S.D.W.V. July 8, 2014). Similarly, this Court approved Dr. Blaivas to testify about warnings for BSC products in *Tyree v. Boston Scientific Corporation.*

> [A]s a urologist, Dr. Blaivas is qualified to testify about the risks of implanting the TVT-O and whether those risks were adequately expressed on the TVT-O's IFU. Dr. Blaivas is qualified to render an opinion as to the completeness and accuracy of Ethicon's warnings and—"it follows from that—the extent to which any inaccuracies or omissions could either deprive a reader or mislead a reader of what the risks and benefits" of the TVT-O was when the warnings were published.[7]

See also, Wise v. C.R. Bard, Inc., 2015 WL 521202, *5, *14 (S.D.W.Va. 2015) ("A urogynecologist…is qualified to make this comparison [whether the product's risks were adequately conveyed in the IFU]."; "as an experienced urogynecologist, [the plaintiff's expert] may testify about the risks he perceives that the [defendant's mesh] product poses to patients and then opine that the [product's] IFU did not convey those risks.").

As one of the first users of a transvaginal mesh kit device in the United States, a prolific teacher of transvaginal mesh procedures, and a prior consultant with several mesh device manufacturers (including these Defendants), and an author of peer-reviewed, published literature on pelvic repair devices and their complications, Dr. Miklos is well-qualified to render opinions on the adequacy of warnings in the IFU from his expert perspective as a urogynecologist. As Dr.

[7] 10/17/14 Memorandum Opinion and Order (Daubert Motions), Doc. 444 at p. 77, *Tyree v. Boston Scientific Corporation*, 2:12-cv-08633 (quoting *Huskey*, 2014 WL 3362264 at *20).

Miklos explains, "[i]f physicians are not fully and timely informed of all of the information known to the manufacturer bearing on the safety and efficacy of the product, they cannot be expected to perform an adequate risk-benefit analysis or obtain adequate informed consent from their patients." (Miklos Report at 22). Dr. Miklos' opinions regarding the completeness and accuracy of Defendants's IFU's are essential to this case and will aid the jury in evaluating the adequacy of a key document that roadmaps the physician's risk/benefit analysis and ultimately the information that is conveyed (or not conveyed) to the patient. See *Edwards*, 2014 WL 3361923 at *13. Defendants' challenges to Dr. Miklos' opinions on warnings contained within the IFU should be denied.

Citing exclusively to his deposition from a prior State court case, Defendants also urge this Court to exclude that Dr. Miklos's warnings opinions because he "is not a FDA regulatory expert," and because he acknowledged in another case that "the FDA looks at things differently than he does." (Defendants' Brief, pp. 9-10). Aside from the fact that the Court has consistently (and correctly) excluded testimony regarding the FDA and its regulations, this argument fails in light of the fact that none of Dr. Miklos's opinions can reasonably be construed to attempt to offer any opinions regarding FDA regulations.[8]

Defendants' final argument, that Dr. Miklos cites no "scientific evidence" for his warnings opinions (Defendants' Brief, pp. 10-11), also must fail. The general legal standard for a failure to warn claim is whether the manufacturer/seller knew or should have known of information relating to risks associated with its products, or the frequency, severity and duration

[8] The only mention of the FDA in Dr. Miklos's Report is in setting forth the relevant factual background that the TVT-S device was withdrawn from the market after the FDA issued a 522 Order requiring proof of the safety and efficacy of the device, and the fact that Ethicon's 510(k) for the TVT-S references the TVT retropubic and TVT-O devices as "substantially equivalent" predicates. Neither of these factual references could even arguably be construed as an attempt to offer any sort of "regulatory opinion."

of those risks, that were not adequately disclosed to the product's user. Dr. Miklos cites to internal documents demonstrating that the Defendants were aware of several risks, including those identified in Defendants' Brief as allegedly lacking "scientific evidence," that were not disclosed to doctors who would ultimately use these products. (Miklos Report, pp. 19-24 and accompanying endnotes citing to numerous internal Ethicon documents). Given that this information came directly from the Defendants' own internal documents, and thus was clearly known or knowable to the company, Defendants' challenge to Dr. Miklos's testimony is ill-founded. As Dr. Miklos explains in his Report, this is information that physicians using these products would expect to be told by the manufacturer/seller in making their decision whether to use these products or in properly consenting their patients whether to have this product permanently implanted into their body. To the extent Defendants apparently intend to contest the scientific validity of information that comes from its own internal documents, that may present an interesting argument that the jury can consider; it does not limit Dr. Miklos's ability to testify regarding what was plainly known to the Defendants that should have been made known to doctors using their product or to patients being implanted with that product.

IV. DEFENDANTS' CONTENTION REGARDING THE ALLEGED "IRRELEVANCE" OF DR. MIKLOS'S OPINIONS REGARDING INADEQUATE TRAINING IS NOT A VALID BASIS FOR A *DAUBERT* CHALLENGE.

Defendants move to exclude Dr. Miklos's opinions regarding the inadequate training provided for the TVT-S because they claim it is "irrelevant." However, relevance is an evidentiary question, perhaps addressed through an objection at trial or a pre-trial motion in limine; it is not a valid basis for *Daubert* motion. Certainly, as a general matter, whether the Defendants properly and adequately trained physicians to implant the TVT-Secur product at least has some "tendency to make a fact [of consequence] more or less probable than it would be

without the evidence," which is the standard for relevance under Federal Rule of Evidence 401. That is particularly true in light of the several defenses and/or allegations in these cases regarding doctor error, improper implantation, and substandard post-implant treatment by implanting or treating physicians. As set forth in detail in Dr. Miklos's Report, the problems associated with the novel TVT-S implantation surgery were exacerbated by a lack of proper training. Relevancy *vel non* should be determined in light of the applicable law and the facts of the case in which the testimony is proffered, not in a vacuum under the guise of a *Daubert* challenge.

Defendants' disavowal of any legal duty to train doctors, as set forth on page 11 of their Brief, perhaps may provide an argument for summary judgment, but it is not a valid *Daubert* challenge.[9] Similarly, the fact that Dr. Miklos testified that he had never seen one TVT-S training document (Defendants' Brief, pp. 11-12) may provide fodder for cross-examination at trial, but it does not render his testimony inadmissible on *Daubert* grounds. *See, e.g.*, *Carlson v. Boston Scientific Corp.*, 2015 WL 1931311 (S.D.W.Va.2015) (denying defense *Daubert* challenge to plaintiff's urogynecologist expert because he allegedly only reviewed one scientific article referencing the product at issue, and instructively holding that "if there are certain device-specific publications that [the expert] failed to review in preparing his expert report, [the defendant] is free to inquire about those publications on cross-examination.").

Defendants' final substantive challenge to Dr. Miklos's training-related opinions, that it "merely regurgitates" internal corporate documents and correspondence, likewise fails. As explained above, Dr. Miklos was consulted by the Defendants regarding the TVT-Secur device

[9] The very fact that Defendants would publicly disclaim any obligation to train doctors to use this relatively radical new surgical procedure with a novel implantation methodology – and putting that responsibility off on hospitals and individual doctors to make sure that they are competent to perform this complex procedure – lends credence to Dr. Miklos's opinions that doctors were not properly trained. It certainly does not render them "irrelevant."

in a cadaver lab led by one of Defendants' physician consultants, and Dr. Miklos provided feedback regarding the necessity to properly train doctors how to perform the technique. (Miklos Report, p. 5). Defendants also sponsored a clinical study in which Dr. Miklos participated to address the safety and efficacy of the TVT-S. The fact that internal documents indicate that Defendants' representatives and employees were expressing some of the same concerns about the need for adequate training in light of the difficulty of the procedure supports his opinions, and his consideration of company documents that inform and correspond with his own knowledge and experience with this product is not a legitimate basis upon which to challenge his opinions.

V. DR. MIKLOS HAS NOT AND DOES NOT INTEND TO OFFER ANY IMPROPER OPINIONS ABOUT ETHICON'S "KNOWLEDGE, STATE OF MIND AND ALLEGED BAD ACTS."

In the final section of their Brief, Defendants seek to exclude any opinions regarding their knowledge or state of mind. However, the only reference to any such opinion are where Dr. Miklos states the factual basis for his opinions regarding failure to warn and inadequate training. In order to offer such an opinion, it is necessary for Dr. Miklos to explain what Ethicon knew or should have known, and that information necessarily comes from Ethicon's documents and/or from the testimony of its representatives. To urge that no expert can ever cite to a company's documents or corporate testimony in forming an opinion is an untenable legal argument.

Dr. Miklos' opinions are properly based, in part, on the information contained in Defendants' internal documents and its corporate testimony. However, citation to Defendants's corporate documents is not an "opinion" – these are some of the facts that form the basis for his opinions. Defendants' internal documents, some of which are cited in support of Dr. Miklos' opinions, are highly relevant to several key issues in these cases, including but not limited to the

defective nature of the design, failure to warn, and the inadequate physician training. Specifically, Defendants' recognition of issues with this product is undeniably important evidence – and Plaintiffs' experts would be remiss if they did not take such information into consideration in forming their opinions. Defendants' efforts to lessen the impact of this damning evidence by misconstruing the nature of Dr. Miklos' testimony that cites to these internal corporate documents is unavailing.

An expert may testify as to his interpretation of internal company documents that he relied on in making his opinion. In *Smith v. Pfizer*, 714 F.Supp.2d 845 (M.D.Tenn.2010), the Court denied a similar *Daubert* motion arguing that the plaintiff's expert had offered improper "state of mind/intent" opinions, stating as follows:

> [Plaintiff's expert] King may properly testify as to his interpretation of internal marketing-related documents that he relied on in forming his opinions. *See In re Seroquel Prods. Liab. Litig.*, No. 6:06–md–1769, 2009 WL 3806436, at *4 (M.D.Fla. July 20, 2009) (holding that expert witnesses may 'rely on and discuss [the defendant's] internal corporate documents.... To rule otherwise would unduly restrict Plaintiffs' experts from explaining the bases of their opinions.'). He may not, however, testify as to the defendants' motives or intent. *Id.* The defendants highlight instances of arguably objectionable portions of King's testimony in previous MDL cases. (*See* Docket No. 119 at 11, 11 n. 12.) But King's statement, which has been filed with the court and will constitute his direct testimony in this case, does not contain any speculation regarding the defendants' motives or intent. (*See* Docket No. 180, Ex. 6.) The court notes that the defendants may object at trial if they believe that King's testimony, outside of his statement, improperly discusses motive or intent.").

See also, In re Yasmin and Yaz (Drospirenone) Prods. Liab. Litig., 2011 WL 6301625 (S.D.Ill.2011) (plaintiffs' OB-GYN experts were qualified to render risk-benefit and warning opinions based, in part, on review of internal corporate documents, and review of such materials – along with peer-reviewed literature – was a reliable methodology for rendering such opinions).

Whether Defendants had information known or available to it bearing on the safety or efficacy of its products is a critical component the adequacy of the warnings provided by

Defendants to physicians and patients. Whether Defendants was aware of other risks, or information that its products could increase the frequency, severity or duration of known risks, bears directly on the question of whether the warnings provided by Defendants were in adequate. Dr. Miklos' opinions examine the warnings in light of information that was known or available to Defendants about the products in question as reflected by Defendants' own internal documents, as well as published medical literature. What information was known to Defendants, but not provided to physicians, is a fundamental element of the failure to warn analysis. Indeed, without the ability to assess what was known – or at least knowable – to Defendants, it would be next to impossible for Dr. Miklos to offer an opinion of what information it should have provided to physicians using these products. Dr. Miklos is not offering any opinion as to Defendants' "state of mind" merely by pointing out what Defendants' own documents show was known to Defendants. Dr. Miklos' consideration of Defendants' corporate documents and opinions concerning the Defendants' IFU and training fall squarely within the parameters previously recognized by this Court – "an expert may testify as to a review of internal corporate documents solely for the purpose of explaining the basis for his or her opinions—assuming the opinions are otherwise admissible. . . ." *In re C.R. Bard, Inc.*, 948 F. Supp. 2d at 610 (S.D.W.V. 2014). *See also*, 10/17/14 Memorandum Opinion and Order (Daubert Motions), Doc. 444 at p. 77, *Tyree v. Boston Scientific Corporation*, 2:12-cv-08633 (quoting *Huskey*, 2014 WL 3362264 at *20).

A review of Dr. Miklos' Report demonstrates that Dr. Miklos relies on a limited number of specific internal documents produced by Defendants that are reflective of information within Defendants' possession and/or knowledge that bear directly on the subject matter of the design defect, failure to warn, inadequate training and general causation opinions that he offers in these

cases. In rejecting a challenge by plaintiffs to defense expert testimony that relied heavily on internal corporate documents, this Court addressed the propriety of this sort of testimony, stating instructively:

> I FIND that *Liberty Media Corp. v. Vivendi Universal, S.A.* provides the appropriate solution to the situation at hand. 874 F.Supp.2d 169, 174 (S.D.N.Y.2012). The Southern District of New York in *Liberty Media* held:
>
> > [The expert] will not be permitted to exhaustively recount all of the facts of the case.... [The expert] will not be permitted to recount the entire history of Vivendi through the class period. Rather, [the expert] must draw on the facts only as necessary—and in as concise a manner as possible—to support his opinion ... which is based on his experience in corporate valuations. I decline to parse [the expert]'s report paragraph-by-paragraph to determine where the report turns from expert analysis to factual narrative. Rather, I trust plaintiffs' counsel will exercise discretion in allocating trial time and will only present the facts necessary to support [the expert]'s opinion. In the event plaintiffs' counsel fails to exercise appropriate discretion, I will cut off any lengthy factual narrative.

Wise v. C.R. Bard, Inc., 2015 WL 521202, *18 (S.D.W.Va.2015).

Consistent with the Court's instructive ruling, Dr. Miklos intends to draw on the important facts of this case, including but not limited to such facts that may be reflected in Defendants' internal corporate documents and testimony, only as necessary to support his opinion. Defendants' arguments about "state of mind" and "factual narratives" are misplaced here, and their motion should be denied.

CONCLUSION

Dr. Mikos is well-qualified and his opinions are reliable. Defendants' challenges are not well-founded factually or legally, and thus Defendants' motion to exclude Dr. Miklos' opinions should be denied.

This 9th day of May, 2016.

By: */s/ Henry G. Garrard, III*

Henry G. Garrard, III
hgg@bbgbalaw.com
Georgia Bar No. 286300
Josh B. Wages
jbw@bbgbalaw.com
Georgia Bar No. 730098
Counsel for the Plaintiffs

Blasingame, Burch, Garrard & Ashley, P.C.
P.O. Box 832
Athens, GA 30603
(706) 354-4000

CERTIFICATE OF SERVICE

I hereby certify that on May 9, 2016, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

By: */s/ Henry G. Garrard, III*

Henry G. Garrard, III
hgg@bbgbalaw.com
Georgia Bar No. 286300
Josh B. Wages
jbw@bbgbalaw.com
Georgia Bar No. 730098
Counsel for the Plaintiffs

Blasingame, Burch, Garrard & Ashley, P.C.
P.O. Box 832
Athens, GA 30603
(706) 354-4000